K013377

DEC 2 0 2001

0. APPLICANT'S NAME AND ADDRESS

Ocular Sciences Inc.
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Concord, CA 94520
USA

Contact Person

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1. IDENTIFICATION OF DEVICE

Common Name:	Soft Contact Lens
Trade Name:	BIOMEDICS®UV Colors (ocufilcon D) Soft (Hydrophilic) Contact lens
Classification:	Daily Wear Soft (hydrophilic) Contact Lens
Device classification:	Class II (21 CFR 886.5925 (b) (1))

2. DESCRIPTION OF DEVICE

The BIOMEDICS® UV Colors (ocufilcon D) Soft (Hydrophilic) Contact Lenses are available with ultraviolet absorbing additive (benzophenone based) and marketed in four colors:

- Blue, Green, Hazel and Grey
- in the power range of –20.00 to +10.00 diopters for sphere,
- with center thickness from 0.025mm to.40mm
- with base curves of 8.00mm to 9.20mm
- with diameter of 12.00mm to 15.00mm

The lenses are made by affixing a color pigment on the front surface of the lens, which corresponds to the iris. The colored pigments consist of Iron Oxide (Black, Russet & Yellow), Titanium Dioxide (White), Carbozole Violet (Violet), Phthalocyanine (Blue & Green), Chromium Oxide (Green). All colored additives used are listed in 21 CFR 73 subpart D and 74 subpart D.

This lens material, packaging, manufacturing and sterilization process is equivalent to BIOMEDICS®UV (ocufilcon D) described in submission PMA890023/S4 and S7, 510(K) K984046.

3. INTENDED USE

BIOMEDICS® UV Colors spherical lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The BIOMEDICS® UV Colors (ocufilcon D) Soft (Hydrophilic) Contact Lens are indicated for daily wear to enhance or alter the apparent color of the eye. The eye care practitioner may prescribe the contact lens for either single use disposable wear and for frequent replacement wear. When prescribed for frequent replacement/planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting systems.

The Biomedics® UV Colors Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

4. PREDICATE DEVICES

The predicate lenses were selected to address: material (FDA Group IV: high water, ionic polymer), intended use (daily wear) and lens designs (sphere, multifocal).

Lens material, spherical lens design and intended use:

BIOMEDICS® UV (ocufilcon D) Sphere Hydrophilic Contact Lenses, FDA Group IV, high water content, ionic soft contact lenses for daily wear marketed internationally by OCULAR SCIENCES Inc. under PMA 890023/S7 and K984046.

Opaque colored lens:

FRESHLOOK Colorblends (phemfilcon A) Sphere (Hydrophilic) Contact lenses marketed internationally by Wesley Jessen under PMA 830037 S33/S39 and K954603.

5. CHARACTERISTICS

The characteristics of the Biomedics® UV Colors are compared to the characteristics of the predicate device Biomedics® UV sphere in the following table.

TABLE 1

Material comparison				
	Predicate device **BIOMEDICS® UV Sphere**		Subject device **BIOMEDICS® UV Colors**	
PRODUCTION METHOD	Cast molded process		Cast molded process	
INTENDED USE	Extended and daily wear Correction of ametropia		Daily wear Correction of ametropia	
MATERIAL	ocufilcon D		ocufilcon D	
Type	Group IV		Group IV	
Color additive	Vat Blue 6 Dye 21 CFR 73.3119 CAS #130-20-1		Iron Oxides 21 CFR 73.3125 Titanium Dioxide 21 CFR 73.3126 Carbazole Violet 21 CFR 73.3107 Copper Phthalocyanine Blue 21 CFR 74.3045 Copper Phthalocyanine Green 21 CFR 73.3124 Chrome Oxide 21 CFR 73.3111	
UV additive	Yes		Yes	
Characteristics comparison	*Measured*	*Labeled*	*Measured*	*Labeled*
Water Content % @ 20°C	54.1	55	53.8	55
Refractive Index @ 20°C	1.405	1.41	1.405	1.41
Dk permeability, ISO 9913-1 Polarimetric method with edge correction @ 35°C x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg)	17.4	19.6	17.4	19.6
Elongation at break, % @ 20°C	80	NA	80	NA
Mechanical strength, Mpa @ 20°C	0.52	NA	0.52	NA
Light transmittance	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97.4	(between 400 and 800 nm) 97%	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97.8	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97%

TABLE 2

Parameter comparison				
	Predicate device **BIOMEDICS® UV**		Subject device **BIOMEDICS® UV Colors**	
Characteristics comparison, -7.00 D 40 lenses	*Labeled*	*Measured*	*Labeled*	*Measured*
Base Curve, mm	8.60	8.55 ± 0.021	8.60	8.49 ± 0.027
Diameter, mm	14.20	14.13 ± 0.03	14.20	14.20 ± 0.008
Power, D	-7.00	-7.48 ± 0.087	-7.00	-7.34 ± 0.123

TABLE 3

Opaque (Colors) lens comparison		
	Predicate device **FRESHLOOK COLORBLENDS**	Subject device **BIOMEDICS®UV Colors**
Indications	Extended and Daily Wear	Daily Wear
Pigments	Iron Oxides 21 CFR 73.3125 Titanium Dioxide 21 CFR 73.3126 Copper Phthalocyanine Blue 21 CFR 74.3045 Copper Phthalocyanine Green 21 CFR 73.3124 Chrome Oxide 21 CFR 73.3111 Carbazole Violet 21 CFR 73.3107	Iron Oxides 21 CFR 73.3125 Titanium Dioxide 21 CFR 73.3126 Copper Phthalocyanine Blue 21 CFR 74.3045 Copper Phthalocyanine Green 21 CFR 73.3124 Chrome Oxide 21 CFR 73.3111 Carbazole Violet 21 CFR 73.3107
Tint Process	Pad Printing	Pad Printing
Print Zone	corresponds to the iris	corresponds to the iris
Location of print	Front surface	Front surface
Manufacturing method	Cast molded	Cast molded

6. NON CLINICAL STUDIES

Non-clinical studies are summarized below:

Chemistry

- Material property data were generated on the BIOMEDICS® UV sphere and the BIOMEDICS® UV™Colors lenses. The material properties were substantially equivalent.
- The lens care product manufacturers have previously shown compatibility of Group IV lenses with their products.
- The shelf life stability for BIOMEDICS® UV Colors lenses is based upon stability protocols included with this notification.
- Studies were conducted to determine the residual monomers on the subject device and on the predicate device. The levels of residual monomers were substantially equivalent. HEMA, MA, EDGMA and UV Blocker.
- Color extraction study was conducted to assess the color fastness of the pigments used to print the Colors lens. The pigments were not detected in the saline extracts above the detection limit for each of the pigments in any of the samples.

Toxicology, lenses materials

In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the BIOMEDICS® UV Colors containing UV blocker. Blue and Red Printed lenses (worst case scenario) were used in the studies. The results are summarized below:

- *Cytotoxicity Test*:

A Cytotoxicity Test has been conducted on the subject device according to ISO 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: In vitro Methods guidelines, was conducted on the test articles, to determine the potential for Cytotoxicity.

The negative controls and the positive controls performed as anticipated. Under the conditions of the study, the test articles were not cytotoxic.

- *Acute Systemic Injection Test in the mouse*:

An evaluation of the test articles for systemic toxicity in mice after a single intravenous administration or a single intraperitoneal administration has been conducted according to the ISO 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.
No evidence of systematic toxicity was observed from the test article extracts. Each test article met the test requirements.

- *Ocular Eye Irritation Test in the rabbit*:

An evaluation of the ocular irritation of 0.9% NaCl and cottonseed oil extracts of the subject article after a single instillation in the rabbit has been conducted according to ISO 10993:Biological Evaluation of Medical devices, Part 10: Tests for the Irritation and Sensitization.
No evidence of ocular irritation was observed in the rabbits. The test article extracts are not considered irritants to the ocular tissue of rabbits.

Solution Compatibility
Microbiology: The lens care product manufacturers have established a reasonable assurance of disinfection efficacy of their care products with lens groups for which they are approved.
Solution compatibility was performed using Allergan 1-Step, Allergan Complete and Essilor (OSL) Concerto. There was no visual difference in color or color intensity between any of the colored printed lenses, with or without cleaning.

Non-clinical studies and manufacturing information provided by reference PMA890023 S4/S7 and K984046

- Cast molded manufacturing process
- Packaging process
- Toxicology packaging materials
- Microbiology and sterilization

7. CLINICAL DATA

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the Biomedics® UV Colored lenses. This determination was based on the following:

- The Biomedics® UV Colors lenses were proven to be substantial equivalent to the predicate Biomedics® UV Sphere lenses (PMA890023/S4 and S7 and K984046). Showed substantial equivalence in physiochemical characteristics and parameters.

The Biomedics® UV Colors lens design was proven to be equivalent to the predicate device: FRESHLOOK Colorblends (phemfilcon A) Sphere (Hydrophilic) Contact lenses marketed internationally by Wesley Jessen under PMA 830037 S33/S39 and K954603.

8. CONCLUSIONS DRAWN FROM STUDIES

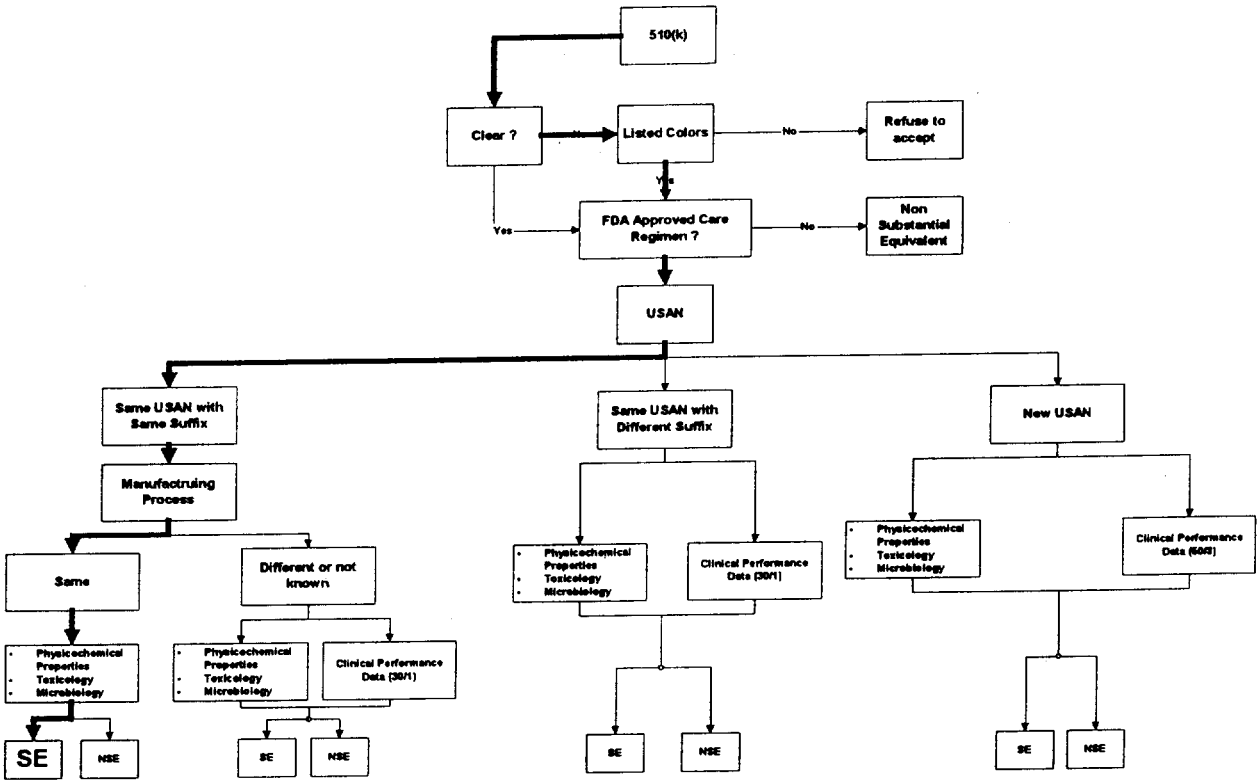
Validity of Scientific Data:
A contract laboratory using Good Laboratory Practices conducted the Toxicology and Color Extraction studies. Chemistry leachables studies were conducted in-house.
Substantial Equivalence:
Information provided in this 510K establishes that the Biomedics® UV Colors lenses are equivalent in optical, chemical and physical properties of the predicate devices and do not raise any questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate devices, Biomedics® UV (ocufilcon D) Soft (Hydrophilic) Spherical and FRESHLOOK Colorblends (phemfilcon A) Sphere (Hydrophilic) Contact lenses marketed internationally by Wesley Jessen under PMA 830037 S33/S39 and K954603.
Risk and Benefits:

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

9. Route chosen in the Flow Chart for 510 (k) Daily Wear Contact Lens Materials Submission

FIGURE 1

BIOMEDICS® UV Colors



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Ocular Sciences Inc.
c/o Richard Lippman, OD FAAO
Senior Consultant
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K013377
Trade/Device Name: BIOMEDICS®UV Colors (ocufilcon D) Soft (Hydrophilic) Contact lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Daily Wear Soft (hydrophilic) Contact Lens
Regulatory Class: II
Product Code: LPL
Dated: October 11, 2001
Received: October 12, 2001

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION FOR USE STATEMENT

510(k) Number (if known) K013377

Device Name:

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the –counter-use_____

Daniel W. C. Brown, P.H.D.

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K013377